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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/724,396 | 11/28/2000 | James F. Young | 10271-007-999 | 8214 |

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EXAMINER

BROWN, STACY D

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/07/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,396

Applicant(s)

YOUNG ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-199 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-199 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

2. Claims 1-199 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-72 and 85-199, drawn to a method of preventing or treating an RSV infection, classified in class 435, subclass 5.
- II. Claims 73-84, drawn to a pharmaceutical composition comprising SYNAGIS™, classified in class 424, subclass 130.1.

If Applicant elects Group I, further restriction is required. Applicant is required to elect one of the following: SYNAGIS™, AFFF, P12f2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4 and A8c7. If Applicant elects SYNAGIS™, claims 1-72 and 85-199 will be examined. If Applicant elects any of the other amino acid sequences, only claims 1-72, 85-110, 123-148, 156-169 and 171-192 will be examined. In either case, further restriction is required for claim 179. Election of *one* of the following sequences is required: SEQ ID NO: 1, 10, 17, 2, 18, 24, 37, 41, 45, 19, 26, 29, 4, 13, 21, 31, 39, 47, 53, 73, 5, 14, 22, 27, 32, 35, 43, 50, 54, 59, 61, 63, 66, 69, 72, 6 and 15. This is not a species election.

If Applicant elects Group II, further restriction is required. Applicant is required to elect one of the following: SYNAGIS™, AFFF, P12f2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4 and A8c7. If Applicant elects SYNAGIS™, claims 73-84 will be examined. If

Art Unit: 1648

Applicant elects any of the other amino acid sequences, only claims 73-76 and 79-84 will be examined. This is not a species election.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using such as in an assay for detecting RSV antigen.

Restriction between SYNAGIST™, AFFF, P12f2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4, A8c7, SEQ ID NO: 1, 10, 17, 2, 18, 24, 37, 41, 45, 19, 26, 29, 4, 13, 21, 31, 39, 47, 53, 73, 5, 14, 22, 27, 32, 35, 43, 50, 54, 59, 61, 63, 66, 69, 72, 6 and 15 is required because the amino acid sequences are distinct, having variant sequences and properties. It would be burdensome to the Office to search all the antibodies and CDRs individually, and a further burden to search for their use in the methods of preventing and treating RSV infection.

Because these inventions are distinct for the reasons given above and the literature and sequence search required one group is neither required nor co-extensive for any other group, restriction for examination purposes as indicated is proper.

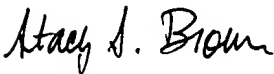
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1648


Conclusion

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
December 5, 2001



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER